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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,052	06/29/2001	Frank J. Bunick	MCP-281	9476

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OH, SIMON J

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1615

DATE MAILED: 05/15/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/896,052

Applicant(s)

BUNICK ET AL.

Examiner

Simon J. Oh

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1615

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 10 March 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-25 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) Other:

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's petition for extension of time and amendment, both received on 10 March 2003.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-4 and 6-16 under 35 U.S.C. 103(a) as being unpatentable over Mehta is withdrawn.

The rejection of Claim 5 under 35 U.S.C. 103(a) as being unpatentable over Mehta in view of Lee is maintained.

Claims 1-4 and 6-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta in view of Lee.

Mehta teaches a chewable, taste-masked pharmaceutical dosage form, preferably in the form of a tablet (See Column 1, Lines 6-28). The components of this dosage form comprise taste-masked microcapsules, which may then be prepared as chewable tablets. The

microcapsules themselves comprise a polymeric coating that masks the taste of the active ingredient, and a pharmaceutical core (See Column 4, Lines 4-12; and Examples 1 and 2). Acetaminophen and ibuprofen are listed among suitable drugs for use in the reference (See Column 7, Lines 31-48; and Claims 11 and 12). Diluents acceptable for use in the microcapsule core include gelatin (See Column 7, Line 59 to Column 8, Line 12). In the given examples, the preferred size of the uncoated acetaminophen particles used lies in the range of 150 to 300 microns (See Column 10, Lines 45-47); and a rationale for such a limitation is given as well (See Column 2, Lines 18-35). The reference also teaches that the coated pharmaceutical cores may then be encapsulated in a hard gelatin capsule or further coated with candy (See Column 9, Lines 35-40). In regards to the limitation of the weight ratio of the drug particles to the outer shell, the examiner sees no criticality in such a feature. The examiner shifts the burden onto the applicant to produce a showing of results that is unexpected by one of ordinary skill in the art that requires such claimed features. Similarly, the examiner is of the opinion that the brittleness limitation presented in Claim 6 is also not critical for the same reason.

Mehta does not teach the use of a unitary, pectin-based core.

Lee teaches a chewable pharmaceutical dosage form comprising of a core containing an active ingredient, and an outer layer (See Figure 2). The core may be in the form of a jelly, with the base of the jelly selected from a group that includes pectin (See Column 2, Lines 29-33). In addition, gelatin may be used in either the core or outer layer to maintain hardness and extension property in the dosage form (See Column 2, Lines 59-61). The outer layer may take a variety of forms, including hard candy (See Column 2, Lines 34-42). Acetaminophen is listed as a possible active ingredient in core (See Column 2, Lines 9-18). In addition, Lee contains what the

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examiner will interpret as an enabling disclosure of a dosage form with a unitary core (See Figure 2; and MPEP § 2125)

It would be obvious to one of ordinary skill in the art to combine the teachings of Mehta and Lee into the objects of the instant application. As stated in *In re Kerkhoven*, 205 USPQ 1069, 1072 (CCPA- 1980), "It is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose." As this court explained in Crockett, 126 USPQ 186, 188 (CCPA- 1960), the idea of combining them flows logically from their having been individually taught in the prior art. Both Mehta and Lee teach a chewable dosage form, comprising of a brittle outer shell and a soft core, which masks the taste of the bitter active ingredients such as acetaminophen and ibuprofen. It is the position of the examiner that one of ordinary skill in the art would be motivated to combine Mehta and Lee in order to create a dosage form that masks taste for the purpose of increasing the likelihood of patient compliance, and that such a dosage form can be produced with a reasonable expectation of success by one of ordinary skill in the art.

As stated above, the Mehta patent discloses the use of uncoated acetaminophen particles in the range of 150 to 300 microns, which, in the view of the examiner, reads on the limitation in the instant claims of active agent particles having an average size of greater than about 50 microns.

Response to Arguments

Applicant's arguments filed 10 March 2003 have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., texture masking of the active agent, and release characteristics of the active agent provided by the instantly claimed dosage form) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

It is the position of the examiner that the applicant's arguments are based upon a narrow interpretation of both the claims and the prior art. It is the position of the examiner that one of ordinary skill in the art, giving both the prior art and the claims in their present form their broadest reasonable interpretation, would find the claimed invention obvious in view of the prior art. See MPEP § 2111 and 2123. In the view of the examiner, such an interpretation is proper and is not, as the applicant alleges, mere speculation. As such, the rejection of Claim 5 over Mehta in view of Lee is maintained, and original Claims 1-4 and 6-16 and new Claims 17-25 are also rejected over Mehta in view of Lee. The prior art therefore reads on the claims, and the claimed invention, as a whole, is *prima facie* obvious.

In the interview of 25 February 2003 (Paper No. 9), suggestions were made for the applicant to further define both the composition of the core and the brittleness of the dosage form. It is noted by the examiner that no such changes have been made to the currently pending claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Examiner
Art Unit 1615

sjo
May 13, 2003

T.K.P.
THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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